



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/578,624

04/12/2007

Akihiko Miyamoto

042269

1499

38834

7590

10/06/2009

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER

YOUNG, RACHEL T

ART UNIT

PAPER NUMBER

3771

NOTIFICATION DATE

DELIVERY MODE

10/06/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary	Application No. 10/578,624	Applicant(s) MIYAMOTO, AKIHIKO	
	Examiner RACHEL T. YOUNG	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).
2. Additionally, the reference JP 2-104052 listed in the IDS dated 5/8/2006 was not considered because it is not in English.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Reference number 10a of figures 10 and 11. Reference number 13d of figures 12 and 13. Reference number 13g of figures 12 and 13. Reference number 14d of figures 14 and 15. Reference number 14b of figures 14 and 15. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to because Fig. 11 contains reference number "3k" that is not pointing to anything. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as

Art Unit: 3771

"amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The disclosure is objected to because of the following informalities: Page 12, line 9 recites "A the same time ", which should be --At the same time--. Page 18, line 18

Art Unit: 3771

recites “can be cur away”, which should be –can be cut away--.

Appropriate correction is required.

5. The use of the trademark “FLUTIDE DISCUS” on page 4, ll. 12 and throughout the entire specification has been noted in this application. The use of the trademark “PULMICORT TURBUHALER” on page 4, ll. 18 and throughout the entire specification has been noted in this application. The use of the trademark “DISKHALER” on page 4, ll. 25 and throughout the entire specification has been noted in this application. The use of the trademark “ROTADISK” on page 16, ll. 24 and throughout the entire specification has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 3771

Claim 1, line 13 recites "an inhalation has been performed without fail", however there is no way to be sure of this without undue experimentation.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 2 recites "comprising", which makes it unclear as to whether the "inhaler aid" or the "reed" are being positively claimed or both.

Clarification is needed.

10. Claim 1 recites the limitation "the minute powdery curative medicine" in lines 5-6 and lines 12-13. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the end" in line 9. There is insufficient antecedent basis for this limitation in the claim. Claim 1 recites the limitation "the inhaler" in line 12.

There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Puderbaugh et al. (6,026,807) in view of Kinkade (5,062,422).

As to claim 1, Puderbaugh discloses an inhaler aid ("spacer" 100) (Fig. 1) with a reed ("reed" 30a) (Fig. 3) for a medicine (Col. 3, ll. 46-47), comprising a main unit ("chamber" 50) (Fig. 1) constituted of a tube (Fig. 1) used to aid an inhaler for the medicine (Col. 2, ll. 41-63), an engagement portion ("mouthpiece" 70) (Fig. 1) which is provided at the upper portion of the main unit (Fig. 1), and a reed fitted into the main unit (Fig. 1), characterized in that when the inhaler aid is joined to a mouthpiece ("discharge outlet" 17) (Fig. 1) of the inhaler ("container" 10) (Fig. 1) for the medicine. Puderbaugh lacks detail regarding that the medicine is a minute powdery curative, however one of ordinary skill in the art at the time the invention was made would consider it an obvious design choice to modify Puderbaugh's inhaler aid such that the medicament was a minute powdery curative that would perform equally as well. Puderbaugh lacks detail regarding that the tube is made of silicon rubber, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the tube be made of silicon rubber, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. Puderbaugh lacks detail regarding that the reed is on the right side of the main unit, however one of ordinary skill in the art at the time the invention was made would consider it an obvious design choice to modify Puderbaugh's inhaler aid such that the reed is on the right side of the main unit, would perform equally as well. Puderbaugh lacks detail regarding that when an inhalation has been performed without fail, a sound is produced from the reed, however Puderbaugh does disclose that a sound is

Art Unit: 3771

produced by the reed when the inhalation inspiratory rate is too high (Col. 4, ll. 6-10).

One of ordinary skill in the art at the time the invention was made would consider it an obvious design choice to modify Puderbaugh's inhaler aid such that the reed produces a sound when the inhalation inspiratory rate is right, which would perform equally as well. Puderbaugh is silent regarding a horn shaped junction and left and right projections comprising holding members at the end. However, Kinkade teaches a mouthpiece capable of attaching to an inhalator (Col. 1, ll. 10-13) with a horn shaped junction ("rolled edge" 6) (Fig. 7) (Col. 2, ll. 66-68) and left ("mouthpiece" 10 on the upper left side in Fig. 1) and right ("mouthpiece" 10 on the upper right side in Fig. 1) projections comprising holding members ("wings" 3) (Fig. 1) at the end. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Puderbaugh's inhaler aid to include a horn shaped junction and left and right projections comprising holding members at the end, as taught by Kinkade, for the purpose of providing comfort to the user during use.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MacRae et al. (2002/0046751 A1) to a nasal inhaler adapter with a reed, Malone (2002/0104531 A1) to a pediatric inhalation device attachment with a whistle, and Foley (5,042,467) to an inhaler attachment with a reed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL T. YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-thurs 7 am - 5:30 pm.

Art Unit: 3771

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771